CHAPTER 10.5.

USA COMMENTS

INFECTION WITH INFECTIOUS SALMON ANAEMIA VIRUS

Article 10.5.1.

For the purposes of the *Aquatic Code*, infection with infectious salmon anaemia virus (ISAV) means *infection* with HPR0 (non-deleted highly polymorphic region) or HPR-deleted ISAV of the genus Isavirus of the family Orthomyxoviridae. Both genotypes should be notified in accordance with the *Aquatic Code*.

There is evidence of a link between non-pathogenic HPR0 ISAV and pathogenic HPR-deleted ISAV, with some outbreaks potentially occurring as a result of the emergence of HPR-deleted from HPR0.

<u>Comment/Citation request</u>: The United States commented on this same item in the ISAV *Manual* chapter, Article 2.3.5.1. We request citations for the "evidence" of a link between non-pathogenic HPR0 ISAV and pathogenic HPR-deleted ISAV.

The provisions in this chapter are provided in recognition of three possible levels of disease status with respect to ISAV:

- 1) HPR0 ISAV and HPR-deleted ISAV free;
- 2) HPR0 ISAV endemic (but HPR-deleted ISAV free);
- 3) HPR0 ISAV and HPR-deleted ISAV endemic.

Information on methods for diagnosis are provided in the Aquatic Manual.

Article 10.5.2.

Scope

The recommendations in this chapter apply to: Atlantic salmon (*Salmo salar*), brown trout (*S. trutta*) and rainbow trout (*Onchorynchus mykiss*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 10.5.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from infection with infectious salmon anaemia virus

In this article, all statements referring to ISAV are for any detectable ISAV, including HPR0 ISAV.

- 1) Competent Authorities should not require any conditions related to infection with ISAV, regardless of the ISAV status of the exporting country, zone or compartment when authorising the importation or transit of the following aquatic animals and aquatic animal products from the species referred to in Article 10.5.2. intended for any purpose and complying with Article 5.4.1.:
 - heat sterilised, hermetically sealed fish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);
 - b) pasteurised fish products that have been subjected to a heat treatment at 90°C for at least 10 minutes (or to any time/temperature equivalent which has been demonstrated to inactivate ISAV);

- mechanically dried, eviscerated fish (i.e. a heat treatment at 100°C for 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate ISAV);
- d) fish oil;
- e) fish meal; and
- f) fish skin leather.
- 2) When authorising the importation or transit of aquatic animals and aquatic animal products of a species referred to in Article 10.5.2., other than those referred to in point 1 of Article 10.5.3., Competent Authorities should require the conditions prescribed in Articles 10.5.10. to 10.5.17. relevant to the ISAV status of the exporting country, zone or compartment.
- 3) When considering the importation or transit of aquatic animals and aquatic animal products from an exporting country, zone or compartment not declared free from infection with ISAV of a species not covered in Article 10.5.2. but which could reasonably be expected to pose a *risk* of transmission for ISAV, *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The exporting country should be informed of the outcome of this assessment.

Article 10.5.4.

Country free from infection with infectious salmon anaemia virus

In this article, all statements referring to a country free from infection with ISAV are for any detectable ISAV, including HPR0 ISAV.

A country may make a *self-declaration of freedom* from infection with ISAV if it meets the conditions in points 1, 2 or 3 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from infection with ISAV if all the areas covered by the shared water are declared countries or *zones* free from infection with ISAV (see Article 10.5.6.).

1) A country where none of the *susceptible species* is present may make a *self-declaration of freedom* from infection with ISAV when *basic biosecurity conditions* have been continuously met in the country for at least the past two years.

OR

- 2) A country where the species referred to in Article 10.5.2. are present but there has been no detectable occurrence of infection with ISAV may make a *self-declaration of freedom* from infection with ISAV when:
 - a) basic biosecurity conditions have been continuously met for at least the past two years; and
 - b) targeted surveillance, as described in Chapter 1.4., has been in place for at least the last two years without detection of infection with ISAV.

- 3) A country that has made a *self-declaration of freedom* from infection with ISAV but in which infection with ISAV is subsequently detected may make a *self-declaration of freedom* from infection with ISAV again when the following conditions have been met:
 - a) on detection of any infection with ISAV, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of ISAV, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

- c) targeted surveillance, as described in Chapter 1.4., has been in place for at least the last two years without detection of infection with ISAV: and
- d) previously existing basic biosecurity conditions have been reviewed and modified as necessary and have continuously been in place for at least two years following since eradication of the disease.

In the meantime, part of the non-affected area may be declared a free *zone* provided that such part meets the conditions in point 3 of Article 10.5.6.

Article 10.5.5.

Country free from infection with HPR-deleted infectious salmon anaemia virus

In this article, all statements refer to a country free from infection with HPR-deleted ISAV but not necessarily free from infection with HPR0 ISAV.

A country may make a self-declaration of freedom from infection with HPR-deleted ISAV if it meets the conditions in points 1, $2_7 \, \underline{\text{or}} \, 3$ er 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from infection with HPR-deleted ISAV if all the areas covered by the shared water are declared countries or *zones* free from infection with HPR-deleted ISAV (see Article 10.5.7.).

A country where none of the susceptible species is present may make a self-declaration of freedom from infection with HPR-deleted ISAV when basic biosecurity conditions have been continuously met in the country for at least the past two years.

OR

12) A country where the species referred to in Article 10.5.2. are present but there has been no observed occurrence of infection with HPR-deleted ISAV for at least the past ten years despite conditions that are conducive to clinical expression, as described in the corresponding chapter of the *Aquatic Manual*, may make a *self-declaration of freedom* from infection with HPR-deleted ISAV when *basic biosecurity conditions* have been continuously met in the country for at least the past ten years.

- 23) A country where the last observed occurrence of infection with HPR-deleted ISAV was within the past ten years or where the disease status prior to targeted surveillance was unknown (e.g. because of the absence of conditions conducive to clinical expression as described in the corresponding chapter of the Aquatic Manual) may make a self-declaration of freedom from infection with HPR-deleted ISAV when:
 - a) basic biosecurity conditions have been continuously met for at least the past two years; and
 - b) targeted surveillance, as described in Chapter 1.4., has been in place for at least the last two years without detection of infection with HPR-deleted ISAV.

- 34) A country that has made a self-declaration of freedom from infection with HPR-deleted ISAV but in which infection with HPR-deleted ISAV is subsequently detected may make a self-declaration of freedom from infection with HPR-deleted ISAV again when the following conditions have been met:
 - a) on detection of infection with HPR-deleted ISAV, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of HPR-deleted ISAV, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and
 - c) targeted surveillance, as described in Chapter 1.4., has been in place for at least the last two years without detection of infection with HPR-deleted ISAV; and
 - d) previously existing basic biosecurity conditions have been reviewed and modified as necessary and have continuously been in place for at least two years following since eradication of the disease.

In the meantime, part of the non-affected area may be declared a free *zone* provided that such part meets the conditions in point 3 of Article 10.5.7.

Article 10.5.6.

Zone or compartment free from infection with infectious salmon anaemia virus

In this article, all statements referring to a zone or compartment free from infection with ISAV are for any detectable ISAV, including HPR0 ISAV.

A zone or compartment within the territory of one or more countries not declared free from infection with ISAV may be declared free by the Competent Authority(ies) of the country(ies) concerned if the zone or compartment meets the conditions referred to in points 1, 2 or 3 below.

1) A zone or compartment where none of the susceptible species is present may be declared free from infection with ISAV when basic biosecurity conditions have been continuously met in the zone or compartment for at least the past two years.

OR

- 2) A zone or compartment where the species referred to in Article 10.5.2. are present but there has been no detectable occurrence of infection with ISAV may be declared free from infection with ISAV when:
 - a) basic biosecurity conditions have been continuously met for at least the past two years; and
 - b) targeted surveillance, as described in Chapter 1.4., has been in place for at least the last two years without detection of infection with ISAV.

- 3) A *zone* previously declared free from infection with ISAV but in which any ISAV is detected may be declared free from infection with ISAV again when the following conditions have been met:
 - a) on detection of infection with ISAV, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of ISAV, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

- c) targeted surveillance, as described in Chapter 1.4., has been in place for at least the last two years without detection of infection with ISAV; and
- d) previously existing basic biosecurity conditions have been reviewed and modified as necessary and have continuously been in place for at least two years following since eradication of the disease.

Article 10.5.7.

Zone or compartment free from infection with HPR-deleted infectious salmon anaemia virus

In this article, all statements refer to a zone or compartment free from infection with HPR-deleted ISAV but not necessarily free from infection with HPR0 ISAV.

A zone or compartment within the *territory* of one or more countries not declared free from infection with HPR-deleted ISAV may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the zone or compartment meets the conditions referred to in points 1, 2_7 or 3 or 4 below.

A zone or compartment where none of the susceptible species is present may be declared free from infection with HPR-deleted ISAV when basic biosecurity conditions have been continuously met in the zone or compartment for at least the past two years.

OR

<u>12</u>) A zone or compartment where the species referred to in Article 10.5.2. are present but there has been no observed occurrence of infection with HPR-deleted ISAV for at least the past ten years despite conditions that are conducive to its clinical expression, as described in the corresponding chapter of the Aquatic Manual, may be declared free from infection with HPR-deleted ISAV when basic biosecurity conditions have been continuously met in the zone or compartment for at least the past ten years.

OR

- 23) A zone or compartment where the last observed occurrence of infection with HPR-deleted ISAV was within the past ten years or where the disease status prior to targeted surveillance was unknown (e.g. because of the absence of conditions conducive to clinical expression as described in the corresponding chapter of the Aquatic Manual) may be declared free from infection with HPR-deleted ISAV when:
 - a) basic biosecurity conditions have been continuously met for at least the past two years; and
 - b) targeted surveillance, as described in Chapter 1.4., has been in place for at least the last two years without detection of infection with HPR-deleted ISAV.

- 34) A zone previously declared free from infection with HPR-deleted ISAV but in which infection with HPR-deleted ISAV is detected may be declared free from infection with HPR-deleted ISAV again when the following conditions have been met:
 - a) on detection of infection with HPR-deleted ISAV, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of HPR-deleted ISAV, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and
 - targeted surveillance, as described in Chapter 1.4., has been in place for at least the last two years without detection of infection with HPR-deleted ISAV; and
 - d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least two years following since eradication of the *disease*.

Article 10.5.8.

Maintenance of free status for infection with infectious salmon anaemia virus

In this article, all statements referring to a country, zone or compartment free from ISAV are for any detectable ISAV, including HPR0 ISAV.

A country, *zone* or *compartment* that is declared free from infection with ISAV following the provisions of point 1 of Articles 10.5.4. or 10.5.6. (as relevant) may maintain its status as free from infection with ISAV provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from infection with ISAV following the provisions of point 2 of Articles 10.5.4. or 10.5.6. (as relevant) may maintain its status as free from infection with ISAV provided that *targeted surveillance* is continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*, and *basic biosecurity conditions* are continuously maintained.

Article 10.5.9.

Maintenance of free status for infection with HPR-deleted infectious salmon anaemia virus

In this article, all statements refer to a country, *zone* or *compartment* free from infection with HPR-deleted ISAV, but not necessarily free from infection with HPR0 ISAV.

A country, *zone* or *compartment* that is declared free from infection with HPR-deleted ISAV following the provisions of points 1 or 2 of Articles 10.5.5. or 10.5.7. (as relevant) may maintain its status as free from infection with ISAV provided that *basic biosecurity conditions* are continuously maintained.

A country, zone or compartment that is declared free from infection with HPR-deleted ISAV following the provisions of point 3 of Articles 10.5.5. or 10.5.7. (as relevant) may discontinue targeted surveillance and maintain its free status provided that conditions that are conducive to clinical expression, as described in the corresponding chapter of the Aquatic Manual, exist and basic biosecurity conditions are continuously maintained.

However, for declared free *zones* or *compartments* in an infected country and in all cases where conditions are not conducive to clinical expression, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 10.5.10.

Importation of live aquatic animals from a country, zone or compartment declared free from infection with infectious salmon anaemia virus

In this article, all statements referring to a country, zone or compartment free from ISAV are for any detectable ISAV, including HPR0 ISAV.

When importing live aquatic animals of the species referred to in Article 10.5.2. from a country, zone or compartment declared free from infection with ISAV, the Competent Authority of the importing country should require an international aquatic animal health certificate issued by the Competent Authority of the exporting country or a certifying official approved by the importing country certifying that, on the basis of the procedures described in Articles 10.5.4. or 10.5.6. (as applicable) and 10.5.8., the place of production of the aquatic animal is a country, zone or compartment declared free from infection with ISAV.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11. This Article does not apply to *commodities* referred to in point 1 of Article 10.5.3.

Article 10.5.11.

Importation of live aquatic animals from a country, zone or compartment declared free from infection with HPR-deleted infectious salmon anaemia virus

In this article, all statements refer to a country, *zone* or *compartment* free from infection with HPR-deleted ISAV, but not necessarily free from infection with HPR0 ISAV.

When importing live aquatic animals of the species referred to in Article 10.5.2. from a country, zone or compartment declared free from infection with HPR-deleted ISAV, the Competent Authority of the importing country should require an international aquatic animal health certificate issued by the Competent Authority of the exporting country or a certifying official approved by the importing country certifying that, on the basis of the procedures described in Articles 10.5.5. or 10.5.7. (as applicable) and 10.5.9., the place of production of the aquatic animal is a country, zone or compartment declared free from infection with HPR-deleted ISAV.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11. This Article does not apply to *commodities* referred to in point 1 of Article 10.5.3.

Article 10.5.12.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with infectious salmon anaemia virus

In this article, all statements referring to infection with ISAV are for any detectable ISAV, including HPR0 ISAV.

- When importing, for aquaculture, live aquatic animals of the species referred to in Article 10.5.2. from a country, zone or compartment not declared free from infection with ISAV, the Competent Authority of the importing country should assess the risk and, if justified, apply the following risk mitigation measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of all effluent and waste materials in a manner that ensures inactivation of ISAV.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the Aquatic Code, relevant aspects of the ICES Code (full version see: http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health/disease history;
 - c) take and test samples for ISAV, pests and general health/disease status;
 - d) import and quarantine in a secure facility a founder (F-0) population;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - culture F-1 stock and at critical times in its development (life cycle) sample and test for ISAV and perform general examinations for pests and general health/disease status;
 - g) if ISAV is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the basic biosecurity conditions of the importing country, zone or compartment, the F-1 stock may be defined as infection with ISAV free or specific pathogen free (SPF) for ISAV;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, zone or compartment.
- 4) With respect to point 3e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to aquatic animals referred to in point 1 of Article 10.5.3.

Article 10.5.13.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with infectious salmon anaemia virus

In this article, all statements referring to infection with ISAV are for any detectable ISAV, including HPR0 ISAV.

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 10.5.2. from a country, *zone* or *compartment* not declared free from infection with ISAV, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 10.5.3., or products described in point 1 of Article 10.5.16., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of ISAV or is disposed in a manner that prevents contact of waste with susceptible species. For these commodities Member Countries may wish to consider introducing internal measures to address the risks associated with the commodity being used for any purpose other than for human consumption.

Article 10.5.14.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use from a country, zone or compartment not declared free from infection with infectious salmon anaemia virus

In this article, all statements referring to infection with ISAV are for any detectable ISAV, including HPR0 ISAV.

When importing, for use in animal *feed*, or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of the species referred to in Article 10.5.2. from a country, *zone* or *compartment* not declared free from infection with ISAV, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to and held in *quarantine* for slaughter and processing to products authorised by the *Competent Authority*; and
- water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of ISAV.

This Article does not apply to commodities referred to in point 1 of Article 10.5.3.

Article 10.5.15.

Importation of aquatic animal products from a country, zone or compartment declared free from infection with infectious salmon anaemia virus

In this article, all statements referring to infection with ISAV are for any detectable ISAV, including HPR0 ISAV.

When importing aquatic animal products of the species referred to in Article 10.5.2. from a country, zone or compartment declared free from infection with ISAV, the Competent Authority of the importing country should require an international aquatic animal health certificate issued by the Competent Authority of the exporting country or a certifying official approved by the importing country certifying that, on the basis of the procedures described in Articles 10.5.4., 10.5.5., 10.5.6. or 10.5.76.(as applicable) and 10.5.8. the place of production of the commodity is a country, zone or compartment declared free from infection with ISAV.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11. This Article does not apply to *commodities* referred to in point 1 of Article 10.5.3.

Article 10.5.15bis

Importation of aquatic animal products from a country, zone or compartment declared free from infection with HPR-deleted infectious salmon anaemia virus

In this article, all statements refer to a country, zone or compartment free from infection with HPR-deleted ISAV, but not necessarily free from infection with HPR0 ISAV.

When importing aquatic animal products of the species referred to in Article 10.5.2. from a country, zone or compartment declared free from infection with HPR-deleted ISAV, the Competent Authority of the importing country should require an international aquatic animal health certificate issued by the Competent Authority of the exporting country or a certifying official approved by the importing country certifying that, on the basis of the procedures described in Articles 10.5.5. or 10.5.7.(as applicable) and 10.5.9., the place of production of the commodity is a country, zone or compartment declared free from infection with infection with HPR-deleted ISAV.The certificate should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to commodities referred to in point 1 of Article 10.5.3.

Article 10.5.16.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from infection with infectious salmon anaemia virus

In this article, all statements referring to infection with ISAV are for any detectable ISAV, including HPR0 ISAV.

- Competent Authorities should not require any conditions related to infection with ISAV, regardless of the ISAV status of the exporting country, zone or compartment when authorising the importation or transit of the following commodities which have been prepared and packaged for retail trade and complying with Article 5.4.2.:
 - a) fish fillets or steaks (frozen or chilled).

Certain assumptions have been made in assessing the safety of *aquatic animals* and *aquatic animal products* listed above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

When importing aquatic animals or aquatic animal products, other than those referred to in point 1 above, of the species referred to in Article 10.5.2. from a country, zone or compartment not declared free from infection with ISAV, the Competent Authority of the importing country should assess the risk and apply appropriate risk mitigation measures.

Article 10.5.17.

Importation of disinfected eggs for aquaculture from a country, zone or compartment not declared free from infection with infectious salmon anaemia virus

In this article, all statements referring to infection with ISAV are for any detectable ISAV, including HPR0 ISAV.

- 1) When importing disinfected eggs of the species referred to in Article 10.5.2. for aquaculture, from a country, zone or compartment not declared free from infection with ISAV, the Competent Authority of the importing country should assess the risk associated with at least:
 - a) the ISAV status of the water to be used during the disinfection of the eggs;
 - b) the level of infection with ISAV in broodstock (ovarian fluid and milt); and
 - c) the temperature and pH of the water to be used for disinfection.
- 2) If the *Competent Authority* of the *importing country* concludes that the importation is acceptable, it should apply the following *risk* mitigation measures including:
 - a) the eggs should be disinfected prior to importing, according to the methods described in Chapter 1.1.3.
 of the Aquatic Manual (under study) or those specified by the Competent Authority of the importing
 country; and

| b) | between disinfection and the import, eggs should not come into contact with anything which may affect |
|----|---|
| | their health status. |

Member Countries may wish to consider internal measures, such as renewed *disinfection* of the eggs upon arrival in the *importing country*.

| 3) | When importing disinfected eggs of the species referred to in Article 10.5.2. for aquaculture, from a country, zone or compartment not declared free from infection with ISAV, the Competent Authority of the importing country should require an international aquatic animal health certificate issued by the Competent Authority of the exporting country or a certifying official approved by the importing country attesting that the procedures described in point 2 of this article have been fulfilled. |
|----|---|
| | |

Text deleted